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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,182

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Albert J. Banes

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EXAMINER

PERUNGAVOOR, SATHYANARAYA V

ART UNIT

PAPER NUMBER

2624

MAIL DATE

DELIVERY MODE

04/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,182

Applicant(s)

BANES ET AL.

Examiner

SATH V. PERUNGAVOOR

Art Unit

2624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11,18-20,22,23,25,30-32,36-39,41,43,44,46,53-55,65-67 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-5,7-9,11,18-20,22,23,25,30-32,36-39,41,43,44,46,53-55,65-67 and 69.

DETAILED ACTION

Applicant(s) Response to Official Action

- [1] The response filed on December 18, 2008 has been entered and made of record.

Response to Arguments/Amendments

- [2] Presented arguments have been fully considered, but are rendered moot in view of the new ground(s) of rejection necessitated by amendment(s) initiated by the applicant(s).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- [3] Claims 1-5, 7-9, 11, 18-20, 22, 23, 25, 30-32, 36-39, 41, 43, 44, 46, 53-55, 65-67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giuliano et al. ("Giuliano") [US 6,416,959 B1] in view of Lenhard et al. ("Lenhard") [US 6,881,584 B1].

Regarding claim 1, Giuliano meets the claim limitations, as follows:

A tissue engineered construct analytical imaging system (*i.e. fig. 1*) for use in connection with at least one culture well (*i.e. 4*) having a tissue engineered construct therein (*i.e. cells*) and positionable (*i.e. moving stage*) in an enclosed environment (*i.e. environment chamber*), the system comprising [*fig. 1; col. 6, ll. 16-53*]: an imaging device

positioned to image (*i.e.* 7) the enclosed environment (*i.e. environment chamber*) and configured to obtain three dimensional data reflective (*i.e. obtaining images at multiple focal planes*) of at least a portion of the tissue engineered construct (*i.e. cells*) in a well area of interest in the at least one culture well (*i.e. microwell in the plate*), without the removal of the culture well from the enclosed environment (*i.e. environment chamber*) [*fig. 1; col. 6, ll. 48-53; col. 12, ll. 11-22; col. 19, ll. 6-12*]; and a computer controller (*i.e. 10*) configured to at least one of: (i) receive data from the imaging device [*col. 6, ll. 29-35*]; (ii) analyze the data for determining at least one desired parameter within the well area of interest [*col. 6, ll. 29-35*]; and (iii) output data reflecting results of an analysis [*col. 6, ll. 29-35*].

Giuliano does not explicitly disclose the following claim limitations:

Imaging device being inside the incubator.

However, in the same field of endeavor Lenhard discloses the deficient claim limitations, as follows:

Imaging device (*i.e. 1*) being inside the incubator (*i.e. 2*) [*fig. 1*].

It would have been obvious to one with ordinary skill in the art at the time of invention to modify the teachings of Giuliano with Lenhard and place the imager inside the incubator, the reasoning being to enable top-down imaging [*fig. 1*].

Regarding claim 2, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the imaging device is at least one of a camera, a digital camera, a scanner, a scanning device, a plurality of cameras, a video camera, a digital video camera and a device capable of capturing an image [*col. 6, ll. 24*].

Regarding claim 3, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the computer controller is at least one of a computing device, a computer, a personal computer, a controller, a circuit board, a laptop, a personal digital assistant, a networked computer and a server [col. 6, ll. 29].

Regarding claim 4, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the computer controller is further configured to control a mechanical loading mechanism (*i.e.* 305) for loading the tissue engineered construct [fig. 11].

Regarding claim 5, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the at least one culture well is positionable upon the imaging device [col. 6, ll. 20-25].

Regarding claim 7, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the well area of interest includes at least the tissue engineered construct in the culture well [col. 7, ll. 1-10].

Regarding claim 8, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the computer controller is further configured to at least one of expand, contract, manipulate and modify (*i.e.* 104), or any combination thereof, the well area of interest (*i.e.* *antofocus*) [fig. 9].

Regarding claim 9, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein data reflecting a plurality of well areas of interest is obtained by the imaging device [col. 12, ll. 11-22].

Regarding claim 11, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein data reflective of a plurality of well areas of interest is obtained (*i.e.* 105 and 108) by the imaging device for a respective plurality of culture wells positioned within the enclosed environment [fig. 9].

Regarding claim 18, Giuliano meets the claim limitations, as follows:

The system of claim 1, further comprising a storage device (*i.e.* database) in communication with the computer controller and configured to store at least one of the following: data, image data, well culture data, well area of interest data, construct area of interest data, incubator data, parameter data, digital input data, analog input data or any combination thereof [col. 13, ll. 10-25].

Regarding claim 19, Giuliano meets the claim limitations, as follows:

The system of claim 1, further comprising an input device in communication with the computer controller and configured to transmit user input commands to the computer controller [col. 16, ll. 25-30].

Regarding claim 20, Giuliano meets the claim limitations, as follows:

The system of claim 1, further comprising a display device in communication with the computer controller and configured to display at least one of the following: data, image data, well culture data, well area of interest data, construct area of interest data, incubator data, parameter data, digital input data, analog input data, user input data, graphical data, analytical results and images, or any combination thereof [col. 13, ll. 10-20].

Regarding claim 22, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein, after the data is obtained by the imaging device and received by the computer controller, a user can manipulate at least one of the well area of interest and a construct area of interest for use in further data collection for the at least one well culture [col. 19, ll. 28-38].

Regarding claim 23, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the computer controller is further configured to uniquely identify (*i.e.* 116) a culture well in a plurality of culture wells [fig. 9].

Regarding claim 25, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the well area of interest includes a construct area of interest (*i.e.* nucleus), and wherein the desired parameter analyzed is the area of the tissue engineered construct within the construct area of interest [col. 18, ll. 23-27].

Regarding claim 30, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the tissue engineered construct is at least one of the following: tissue, genetic material, bioartificial tissue, bioartificial tendon, a cellular construct and an organic construct, or any combination thereof [col. 16, ll. 1-10].

Regarding claim 31, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the tissue engineered construct is cells cultured in a three-dimensional collagen gel [col. 32, ll. 1-5].

Regarding claim 32, Giuliano meets the claim limitations, as follows:

The system of claim 1, wherein the tissue engineered construct is anchored within the culture well on at least two ends thereof [col. 32, ll. 1-5].

Regarding claim 67, Giuliano meets the claim limitations, as follows:

The method of claim 36, wherein the data is a digital image, the method further comprising pre-defining the desired resolution of the digital image [col. 12, ll. 17-22].

Regarding claims 36-39, 41, 43, 44, 46, 53-55, 65, 66 and 69, all claimed limitations are set forth and rejected as per discussion for claims 1-5, 7-9, 11, 18-20, 22, 23, 25 and 30-32.

Conclusion

[4] Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

[5] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Sath V. Perungavoor whose telephone number is (571) 272-7455. The examiner can normally be reached on Monday to Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Matthew C. Bella whose telephone number is (571) 272-7778, can be reached on Monday to Friday from 9:00am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/576,182
Art Unit: 2624

Page 9

Dated: April 3, 2009

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